Patent
Docket No.: 151-P-08970US02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
John E. Kast et al	Group Art Unit: 3766
Serial No.: 10/772,944	
Filed: February 5, 2004	Examiner: Oropeza, Frances P

For: IMPLANTABLE MEDICAL DEVICE WITH EXTERNAL RECHARGING COIL

AFFIDAVIT UNDER 37 C.F.R. §1.132

STATE OF MINNESOTA)
) ss.
COUNTY OF ANOKA)

John E. Kast, being first duly sworn, does hereby depose and say as follows:

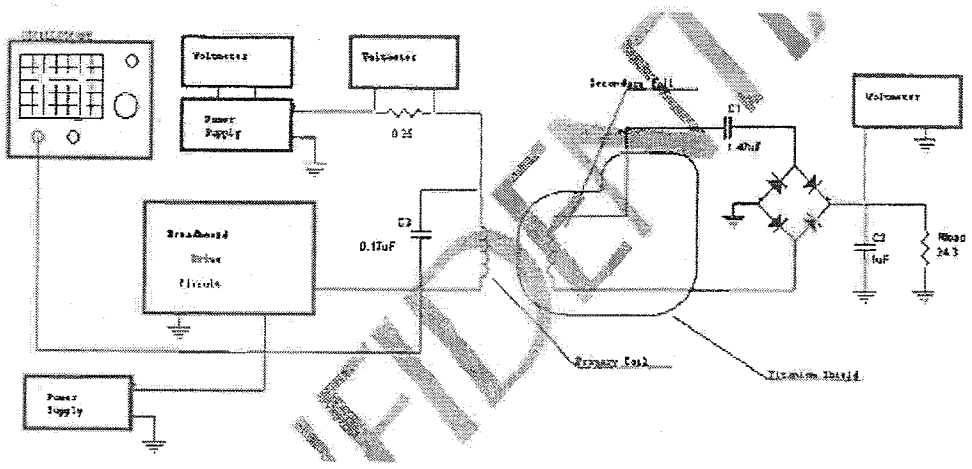
1. That I am the same John E. Kast who is identified as a co-inventor in the above-captioned application.

2. That I received a Bachelor of Science degree in Mechanical Engineering from the University of Minnesota in 1983.

3. That I began working in the Cardiac Rhythm Management division of Medtronic, Inc. in 1984. I joined the Neuromodualtion division within Medtronic in 1999 and have worked there since that time on implantable Neuromodualtion products. I am currently a Senior Principal Systems Technology Engineer.

4. I obtained an implantable medical device having a secondary recharging coil centrally located with respect to the proximal face of the implantable medical device.

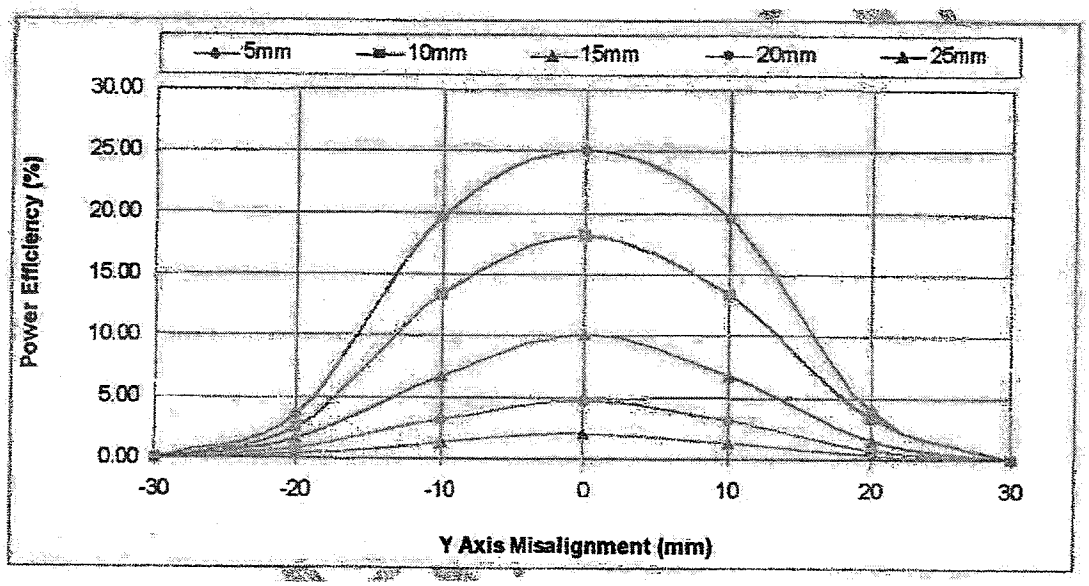
5. I had a vendor test the implantable medical device in an engineering lab with a test system to simulate the implantation of the implantable medical device in a human. The test system is as follows, in which the power supply was set to 24 Volts:

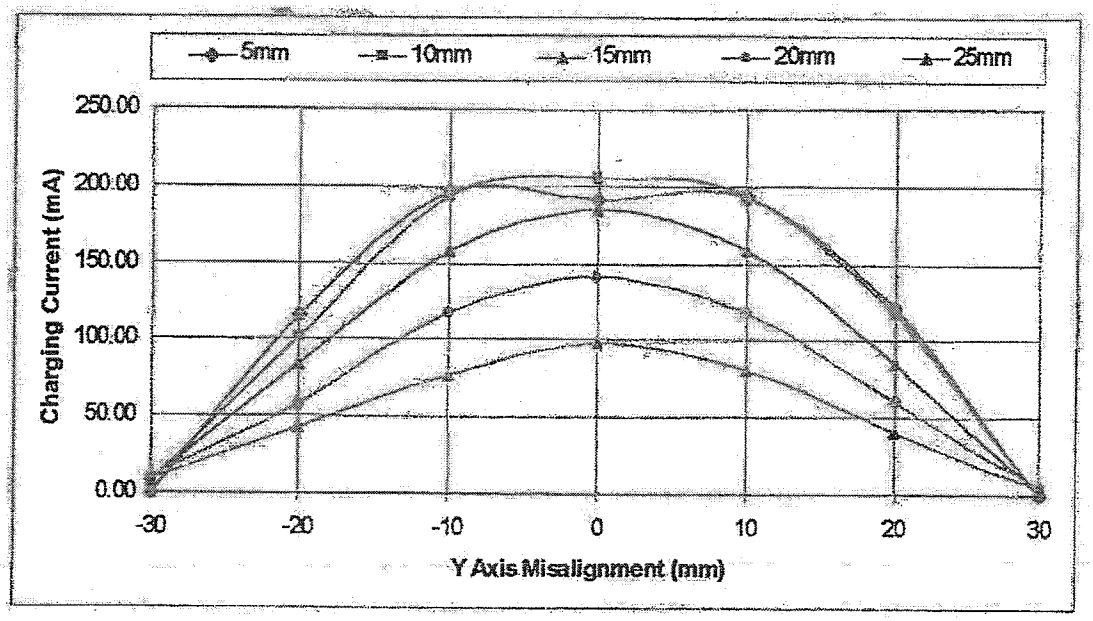


6. The external primary recharging coil was used to simulate recharging of the implantable medical device in a human. A variety of different secondary recharging coils were utilized, but the primary recharging coil was not varied. The location of the external primary recharging coil relative to the secondary recharging coil was changed to different positions for each secondary coil.

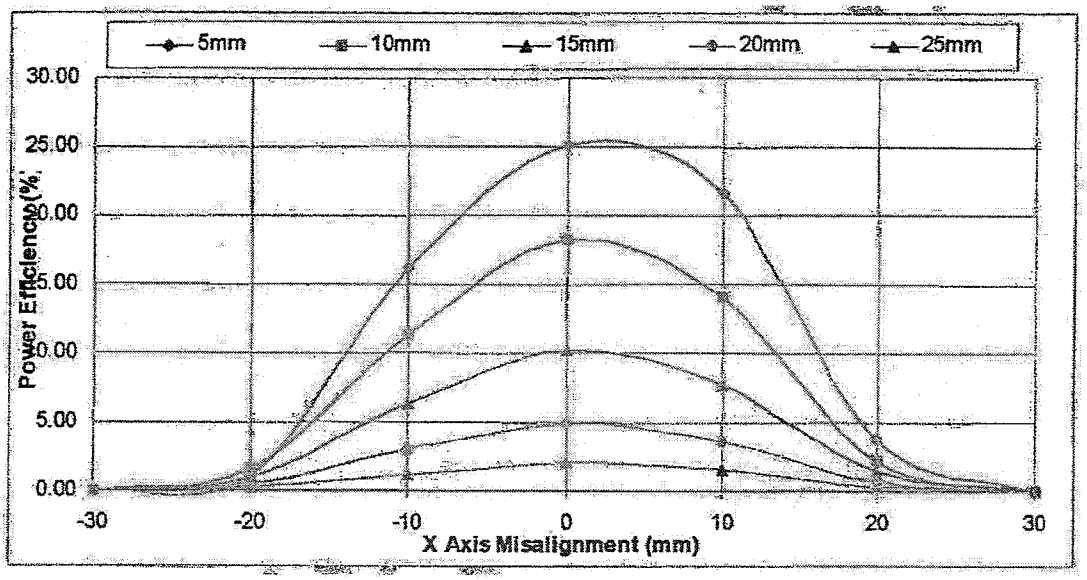
7. The power efficiency and charging current for each secondary coil and for each amount of axial misalignment is presented in the following graphs. The line and symbol of each graph relate to the z-axis separation of the primary recharging coil from the secondary recharging coil.

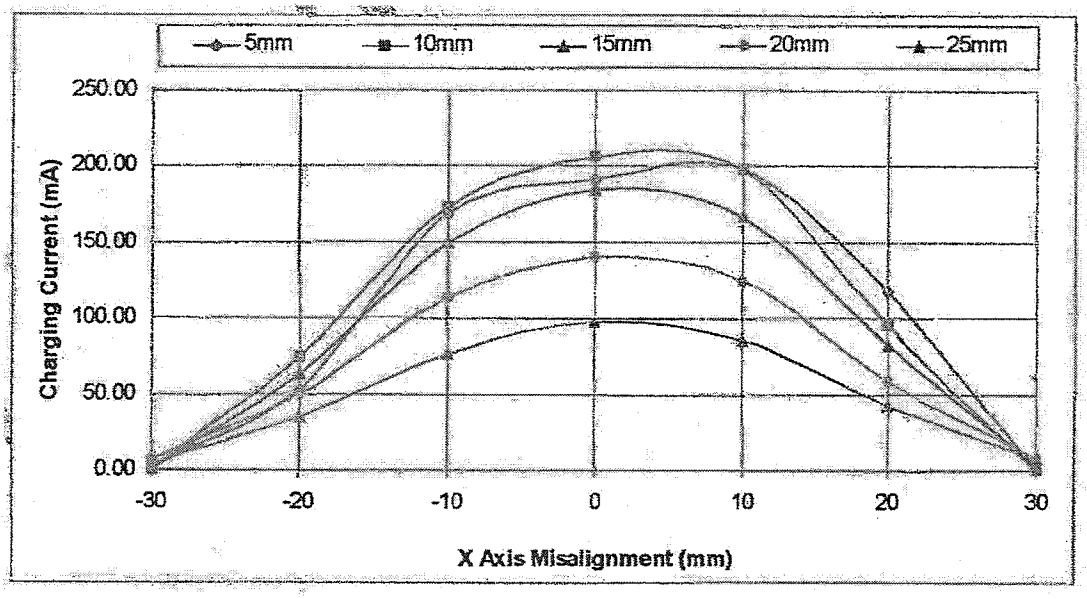
Y Axis Misalignment, Secondary Recharging Coil A



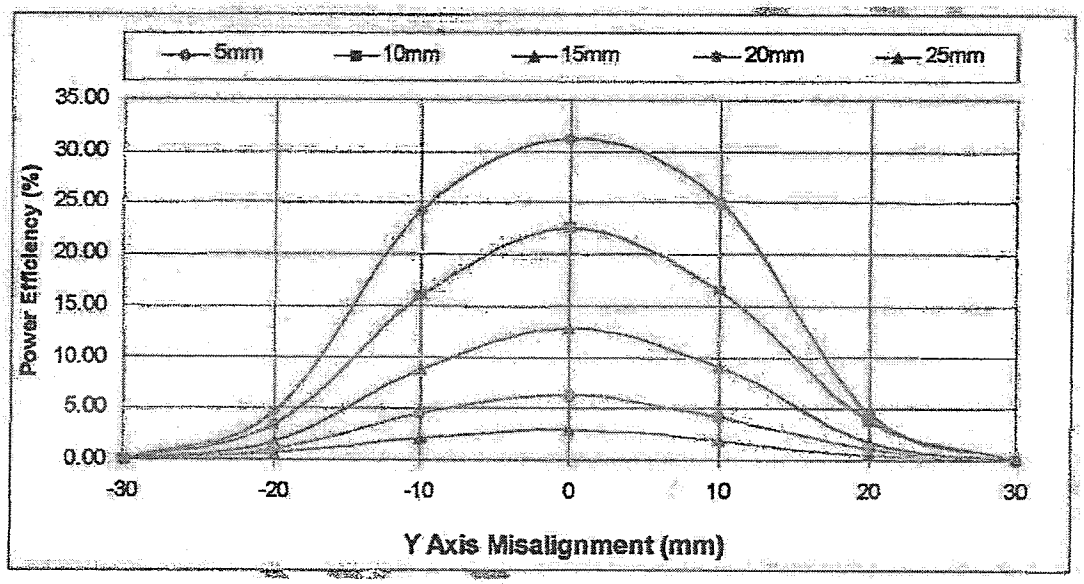


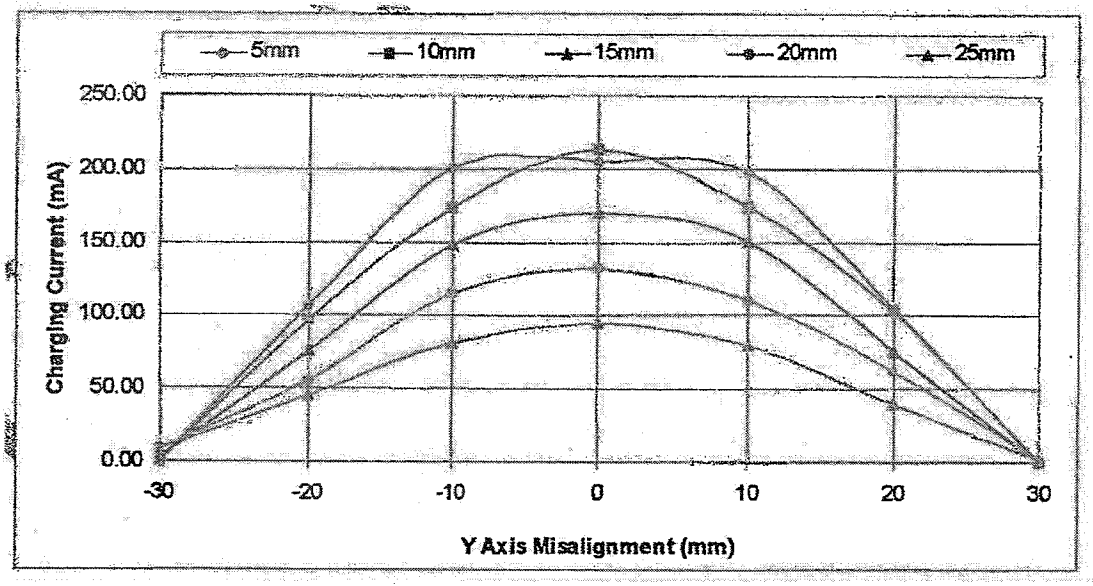
X Axis Misalignment, Secondary Recharging Coil A



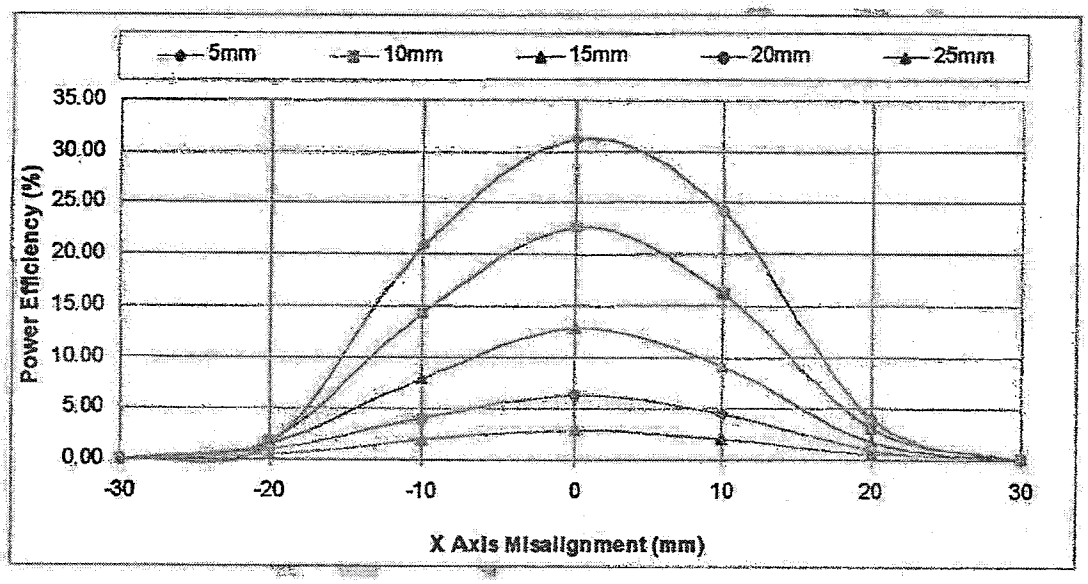


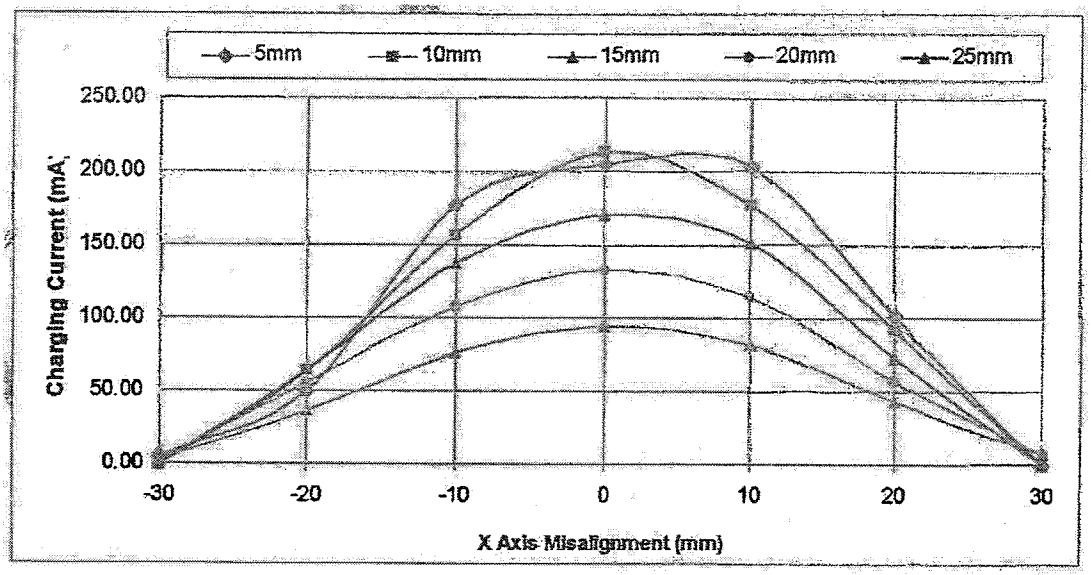
Y Axis Misalignment, Secondary Recharging Coil B



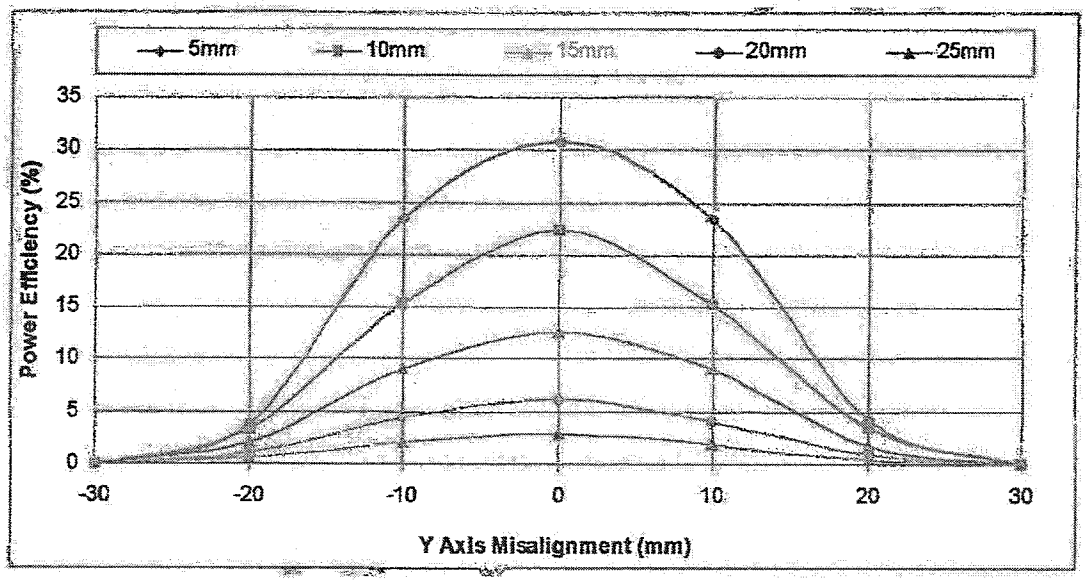


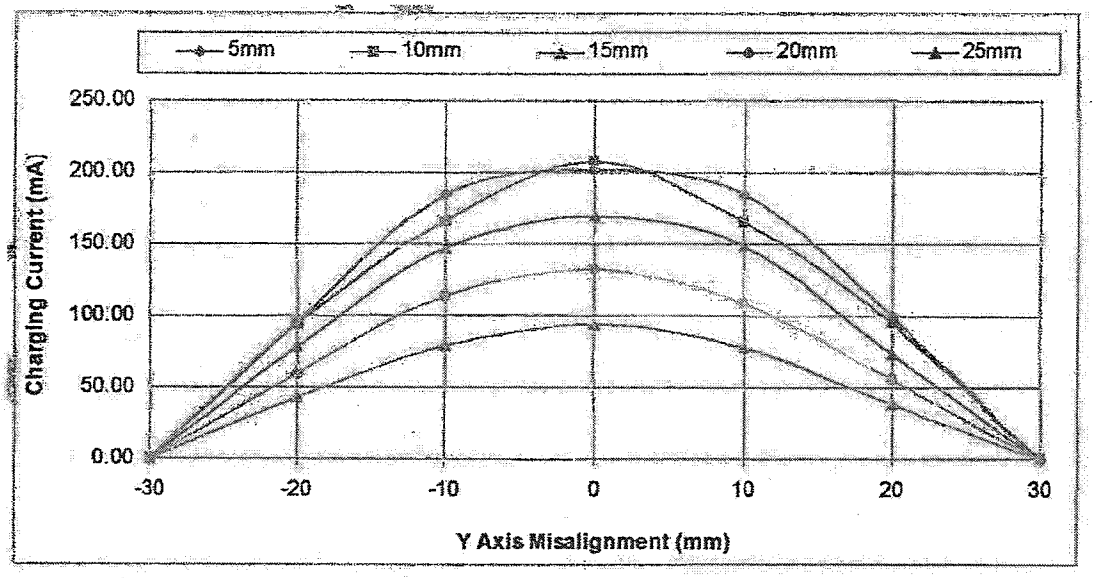
X Axis Misalignment, Secondary Recharging Coil B



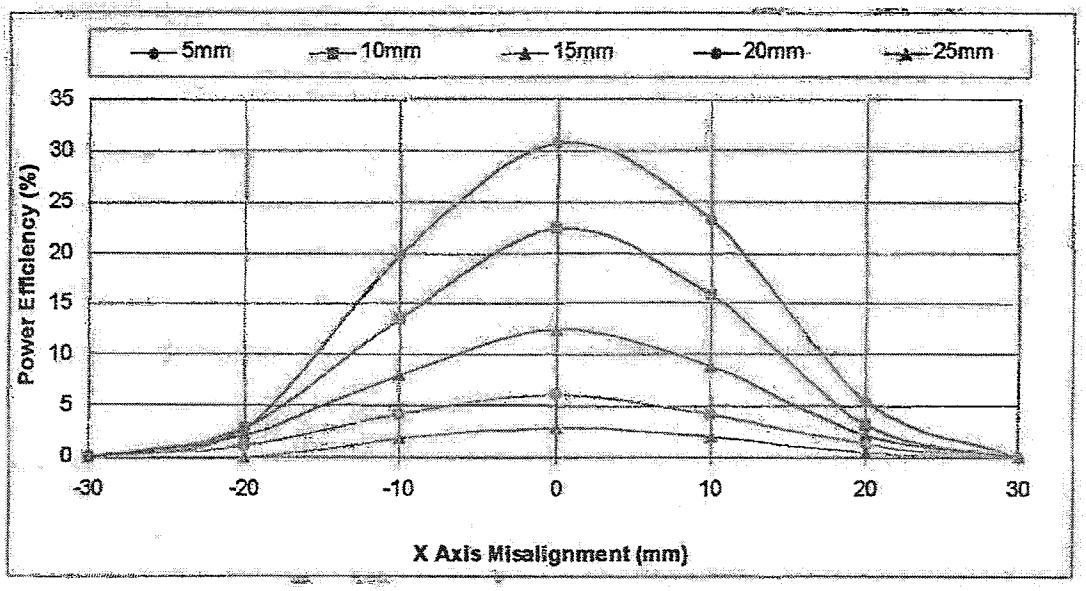


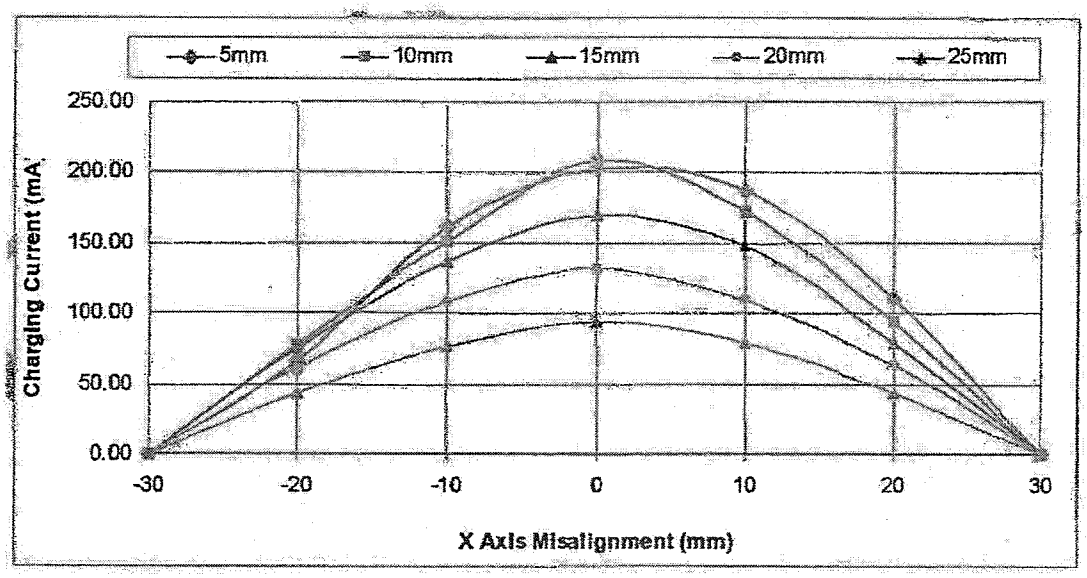
Y Axis Misalignment, Secondary Recharging Coil C



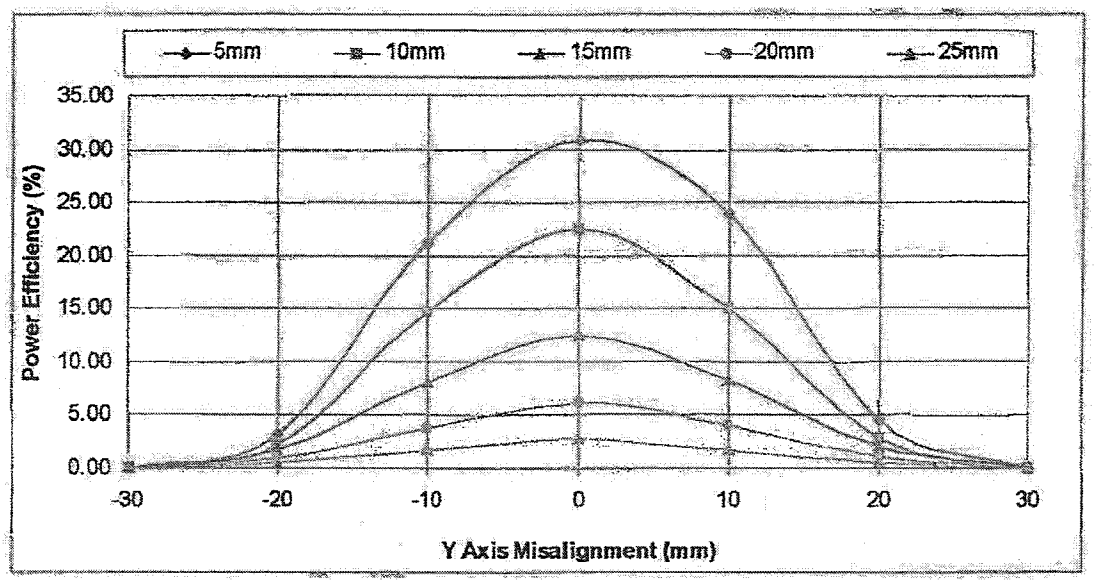


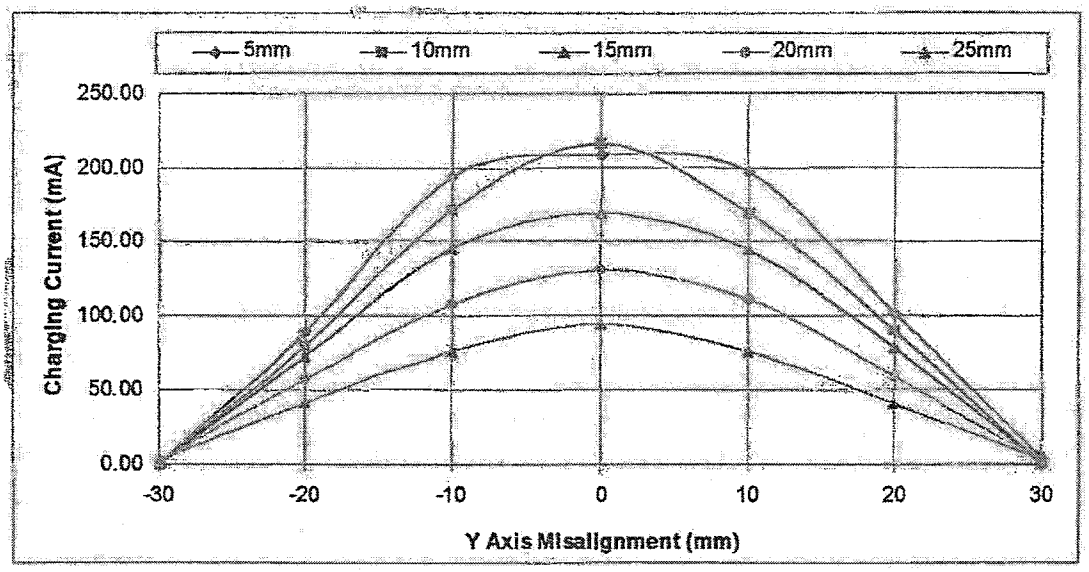
X Axis Misalignment, Secondary Recharging Coil C



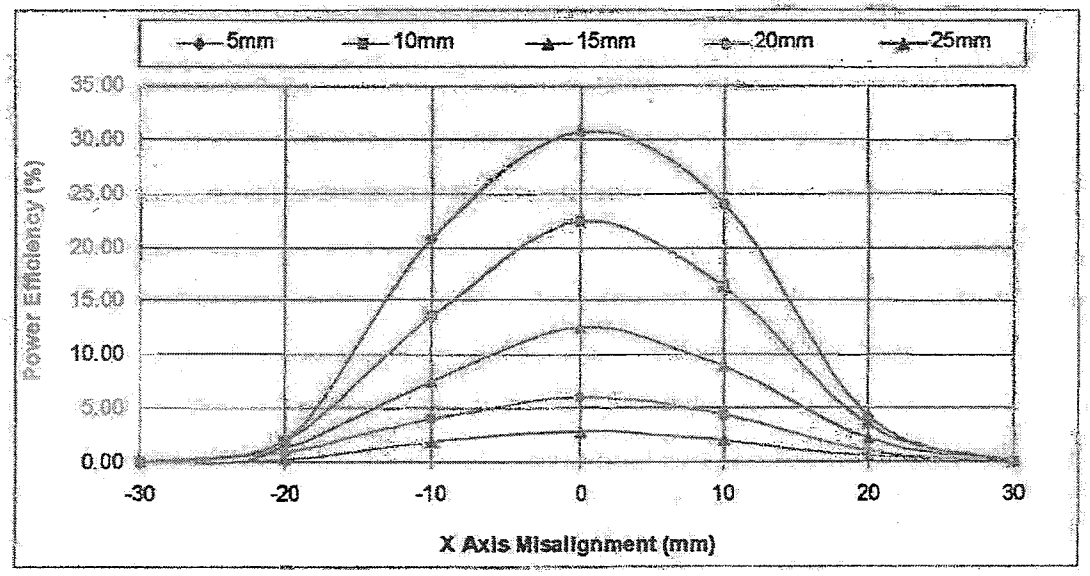


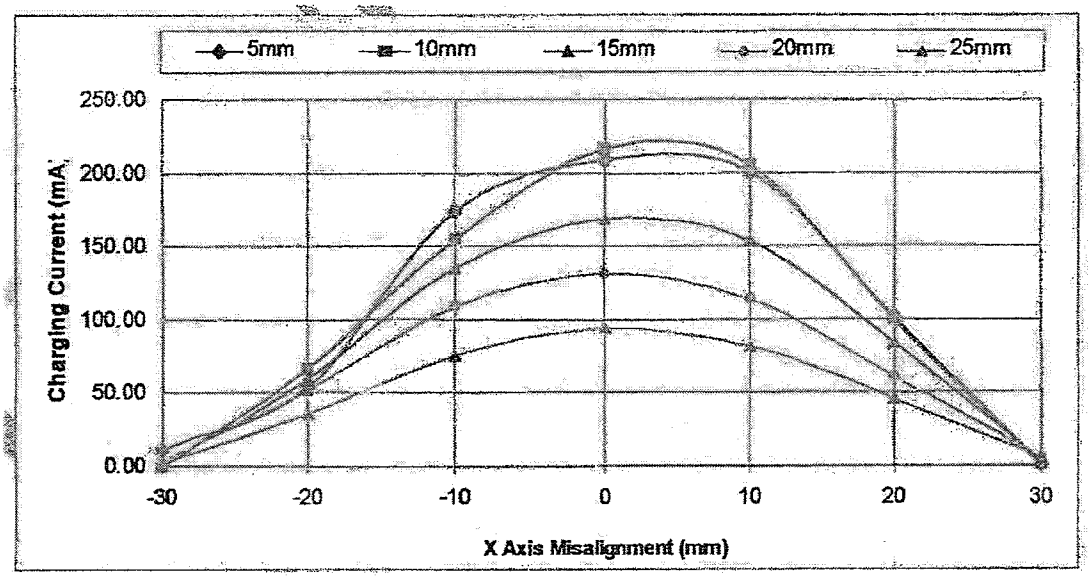
Y Axis Misalignment, Secondary Recharging Coil D





X Axis Misalignment, Secondary Recharging Coil D



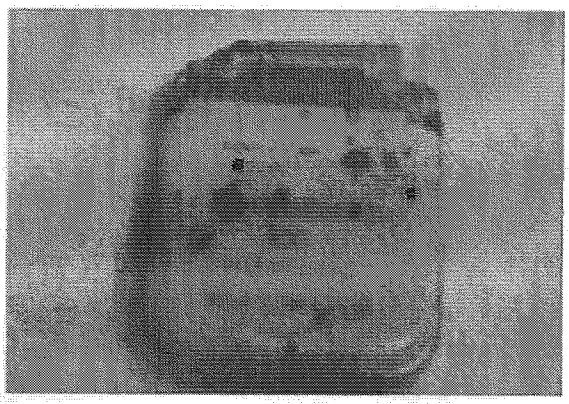


8. These data graphs from paragraph 7 show that to achieve optimal power efficiency and charging current, the primary recharging coil should be oriented as directly concentrically as possible with respect to the secondary recharging coil.

9. Additionally, the implantable medical device was tested in a cadaver lab. The cadaver was utilized to simulate the implantation of the implantable medical device in a human.

10. During testing, users positioned the external primary recharging coil with respect to the implantable medical device. The users established the location of the implantable medical device by palpating the skin of the cadaver, and positioned the primary recharging coil based on the established location. The outer edges of the implantable medical device were the dominant factors for determining the location of where to place the external primary recharging coil.

11. When the user positioned the primary recharging coil with respect to the implantable medical device, a locating piercing fixture was used to determine how concentrically the external primary recharging coil was located with respect to the implantable medical device. The locating piercing fixture functioned by piercing the tissue of the cadaver and making a mark on the implantable medical device in the location of the center of the primary recharging coil. The test was conducted multiple times by multiple testers, and resulted in the following marks created by the locating piercing fixture on the implantable medical device:



12. The data from paragraph 11 establishes that the average location of the user placements of the primary recharging coil with respect to the implantable medical device was approximately in the center of the implantable medical device. The data from paragraph 7 establish that the efficiency of the charge transfer could be optimized by positioning the primary recharging coil as concentrically as possible with the secondary recharging coil.

13. Based on the combination of data from paragraphs 7 and 11, it was determined that the optimal location for the secondary recharging coil with respect to the implantable medical device was as close to the center of the implantable medical device as could be practically achieved. By positioning the secondary recharging coil at the location of the average user placement of the primary recharging coil as determined in paragraph 11, the optimization as determined in paragraph 7 would be most likely to be achieved by the average user.

Further affiant saith not.

John E. Kast

Subscribed and sworn to before me
this 10th day of February, 2009.

Theresa C. To
Notary Public

THERESA C. TO
NOTARY PUBLIC-MINNESOTA
My Commission Expires Jan. 31, 2010